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Attachment 3.1-E Page 1 OMB No. 0938-0193

STANDARDS FOR THE COVERAGE OF ORGAN TRANSPLANT SERVICES

Since 1981, the Wisconsin Medical Assistance Program (WMAP) has reimbursed for non-experimental organ transplants performed on WMAP recipients. The Wisconsin Administrative Code prohibits payment for procedures which are experimental in nature. To determine whether a procedure provided by a particular provider is experimental in nature, the Department considers whether the service is a proven and effective treatment for the condition for which it is intended, as evidenced by:

- The current and historical judgement of the medical community, in medical research, studies, journals or treatises;
- The extent to which Medicare and private insurers recognize and provide coverage of the service;
- The current judgement of experts and specialists in the medical specialty area(s) in which the service is applicable and used; and
- The judgement of the Medical Assistance Medical Audit Committee.

The evaluations are made on a procedure-by-procedure, institution-by-institution basis.

Medical Assistance Medical Audit Committee (MAMAC) Criteria Pertinent to Organ Transplant Programs

The selection criteria utilized by the MAMAC in recommending approval of organ transplant programs to the Department include:

- The program must document the qualifications by training and experience of those individuals involved in all support services required and the adequacy of the physical facilities and equipment required.
- The program must demonstrate the effectiveness of the procedure including published and unpublished data to support its expectation of successful results and the effectiveness of related programs.
- The program must have appropriate preparation in place before consideration of approval.

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STANDARDS FOR THE COVERAGE OF ORGAN TRANSPLANT SERVICES, continued

Medical Assistance Medical Audit Committee (MAMAC) Criteria Perlinent to Organ Transplant Programs, continued

- The program must have arrangements for required follow-up care available and convenient for the circumstances.
- The organ transplant providers must accept Wisconsin Medical Assistance recipients and rates
 of reimbursement.
- The program must have adequate medical criteria for the selection of patients undergoing the procedure. Factors considered relevant may include age, overall health status, patient histories (including possible active drug/alcohol dependence), that will affect the likely success of the transplant procedure.
- In making the selection of patients undergoing the procedure, the program treats similarly situated individuals alike.
- Any restriction on the facilities or practitioners which may provide organ transplant procedures is consistent with the accessibility of high quality care to individuals eligible for the procedures under this State plan.
- All of the above criteria must be satisfied.

Coverage Criteria

In order for a transplant to be a covered Medicaid service, the following criteria must apply:

Bone Marrow Transplants

Diagnoses/clinical conditions include but are not limited to Alder's-Schonberg syndrome, aplastic anemia, bare lymphocyte syndrome, Burkitts B-cell Acute Lymphoblasitic Anemia, germ cell cancer, Hodgkin's, infantile malignant osteoporosis, leukemia (acute and chronic), malignant melanoma, neuroblastoma (Stage IV), primitive neuroectodermal tumor (PNET) (multifocal), severe combined imunodeficiency, Wiscott-Aldrich syndrome.

Limited to tertiary care centers that have the capacities and physician staffing appropriate to the performance of this highly demanding procedure.

Heart Transplant

Diagnoses/clinical conditions include but are not limited to end-stage heart disease resulting from primary cardiomyopathy, congenital heart disease, valvular disease and end-stage coronary artery disease.

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STANDARDS FOR THE COVERAGE OF ORGAN TRANSPLANT SERVICES, continued

Coverage Criteria, continued

Heart-Lung and Lung Transplants

Diagnosis/clinical conditions include but are not limited to cystic fibrosis, cor pulmonale, pulmonary fibrosis, alpha 1 antitrypsin deficiency, pulmonary thromboembolism, chronic obstructive pulmonary disease.

Liver Transplants

Diagnosis/clinical conditions include but are not limited to end-stage renal disease resulting in biliary atresia, alcohol-related liver cirrhosis/hepatitis (requires abstinence of six months or more preceding the transplant and has successfully completed a certified AODA program), cancer of liver (primary hepatoma or cholangiolytic carcinoma), chronic active hepatitis, fulminant hepatic failure of pregnancy, hepatic failure due to hepatic toxins, hepatic vein thrombosis (Budd-Chiari syndrome), hepatitis B (when gamma globulin is administered before and 11 months after transplant), certain inborn errors in metabolism resulting in end-stage liver damage, and miscellaneous metabolic diseases.

Diagnosis/clinical conditions not included are AIDS, primary hepatic malignancy with extension outside liver or metastases, secondary hepatic malignancy, or the recipient's chronological age or concurrent physical deterioration significantly militates against a successful outcome.

Pancreas Transplants

Diagnosis/clinical conditions include but are not limited to diabetes mellitus with severe complications such as end-stage kidney disease, progressive severe visual disturbance, and severe neurological disorder.

Prior Authorization Criteria for Bone Marrow and Stem Cell Transplants

For bone marrow and stem cell transplants, the hospital in which the transplant will be performed must obtain prior authorization from the Department's Chief Medical Officer, who determines whether the proposed procedure meets the diagnostic and clinical criteria adopted by the Department. The diagnoses and clinical conditions which support a decision to proceed with bone marrow and stem cell transplants are listed in the section "Coverage Criteria," above.

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